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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,798

10/28/2005

Luis F Angel

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/529,798

Applicant(s)

ANGEL, LUIS F

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,31-38,40,42-46,48-54 and 56-59 is/are pending in the application.
- 4a) Of the above claim(s) 32, 35-37, 40, 43-44, 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,31,33,34,38,42,45,46,48-54 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 29, 31-38, 40, 42-46, 48-54, 56 and 59, drawn to a stent delivery system, classified in class 623, subclass 1.11.
 - II. Claims 57-58, drawn to a method for positioning a stent, classified in class 606, subclass 108.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be used with an apparatus that has a screw or threaded lock.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

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4. Currently, Claims 29 and 56 are generic to the following disclosed patentably distinct species:

<u>Species</u>	<u>Figure(s)</u>
1	1-4 (single pin lock)
2	5-7 (first and second pin locks)
3	8-9 (ratchet lock)

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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8. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. During a telephone conversation with Neal Persky on Tuesday, January 9 2007 a provisional election was made without traverse to prosecute the invention of Group I directed towards Claims 29, 31-38, 40, 42-46, 48-54, 56 and 59, and Species 2. Affirmation of this election must be made by applicant in replying to this Office action. Claims 57-58, which are directed towards Groups II, as well as Claims 32, 35-37, 40, 43-44, and 59 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Specification

11. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 50 recites the limitation "the at least a portion of the bronchoscope" on line 2 of Claim 50. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 29, 42, 45-46, 48-49, 51, 54, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Heyn (U.S. Patent No. **5,201,757**).

Claims 29 and 56: Heyn discloses a first conduit **44**, wherein at least a portion of an endoscope or bronchoscope may be positionable in the first conduit during use, and a second conduit **20**, wherein at least a portion of the first conduit is positionable in the second conduit, wherein the second conduit is configured to contain at least a portion of a stent **18** between the distal ends of the first and second conduits, and wherein the second conduit is configurable to releasably position the stent in a body lumen or air passage during use (Figure 1, col. 5, lines 15-23).

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Claim 42: Heyn discloses a stop **54** positioned approximate the distal end of the stent delivery system between the first and second conduits, wherein the stop is configured to inhibit movement of the stent in a proximal direction relative to the first conduit (Figure 1, col. 5, lines 55-58).

Claims 45-46: Heyn discloses at least a portion of the first and second conduits being partially flexible (col. 2, lines 31-35).

Claims 48-49: Heyn discloses at least a portion of the first and second conduits being configured to inhibit collapse of the first and second conduits upon removal of an endoscope during use (col. 5, lines 63-67 to col. 6, lines 1-5).

Claim 51: Heyn discloses the stent comprising a pulmonary stent, as in is capable of being deployed into pulmonary artery (col. 5, lines 43-54).

Claim 54: Heyn discloses the second conduit comprising a polymer (col. 5, lines 15-18).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn (U.S. Patent No. **5,201,757**) in view of Bui (U.S. Patent No. **6,629,981**).

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Claim 31: Heyn discloses the claimed device except for a first lock configurable to inhibit movement of the first conduit relative to the second conduit during use, and a second lock configurable to inhibit movement of the endoscope relative to the first conduit during use.

Bui teaches a first lock **110** configurable to inhibit movement of the first conduit relative to the second conduit during use, and a second lock configurable to inhibit movement of the endoscope **124** relative to the first conduit during use (Figures 11, 15-17, and col. 9, lines 43-52 and col. 11, lines 8-19). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a first lock and a second lock, as taught by Bui, to Heyn since it was known in the art that undesirable axial movement of coaxial conduits, or sleeves, results in difficult or undesirable deployment or lack of visibility, and therefore inhibiting movement between first and second conduits facilitates deployment of the stent.

9. Claims 33-34 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn (U.S. Patent No. **5,201,757**) in view of **Gunderson** (U.S. Patent No. **5,776,142**).

Claims 33-34: Heyn discloses the claimed device except for a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises a first grip coupled to at least a portion of the first conduit, and a second grip coupled to at least a portion of the second conduit, and one or more pins coupled to the first conduit, wherein at least one of the pins is configurable to inhibit

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portions of the first and second conduits from moving transversely to each other wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip.

Gunderson teaches a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises a first grip **20** coupled to at least a portion of the first conduit, and a second grip **30** coupled to at least a portion of the second conduit, and one or more pins **28** coupled to the first conduit, wherein at least one of the pins is configurable to inhibit portions of the first and second conduits from moving transversely to each other wherein at least a portion of the first grip is configurable to inhibit movement of the second grip in a direction toward a proximal end of the stent delivery system beyond the portion of the first grip (Figure 1, col. 5, lines 7-16). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a lock to inhibit movement of the first conduit relative to the second conduit, as taught by Gunderson, to Heyn since it was known in the art that the movement of the first or inner conduit relative to the second or outer conduit should be controlled so that undesirable deployment or expansion of the stent may be prevented.

Claim 53: Heyn discloses the claimed device except for the first conduit comprising a polymer.

Gunderson teaches a first conduit comprising a polymer (col. 5, lines 43-48). It would have been obvious to one of ordinary skill in the art at the time of invention to

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provide a first conduit comprising a polymer, as taught by Gunderson, to Heyn since it was known in the art that polymer is a biocompatible, flexible material.

10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Heyn (U.S. Patent No. **5,201,757**) in view of **Mikus** (U.S. Patent No. **6,093,194**).

Claim 38: Heyn discloses the claimed device except for a lock configurable to inhibit movement of the first conduit relative to the second conduit during use, wherein the lock comprises a clamp.

Mikus teaches a lock configurable to inhibit movement of a first conduit **70** relative to the second conduit **75** during use, wherein the lock comprises a clamp **77, 78** in order to prevent premature proximal displacement during insertion of the conduits into the body lumen (Figure 7, col. 7, lines 54-67 to col. 8, lines 1-8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a clamp lock, as taught by Mikus, to Heyn in order to prevent premature proximal displacement of the conduits during insertion into body lumen.

11. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Heyn**

(U.S. Patent No. **5,201,757**) in view of **Heller** (U.S. Pub. No. **20030215564**).

Claim 50: Heyn discloses the claimed device except for the endoscope comprising a bronchoscope, and wherein the at least a portion of the bronchoscope being partially flexible.

Heller teaches an endoscope comprising a bronchoscope, and wherein the at least a portion of the bronchoscope being partially flexible (page 4, paragraph 58). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a bronchoscope, as taught by Heller, to Heyn since it was known in the art that in deploying a pulmonary stent, visibility of the pulmonary arteries is facilitated by bronchoscopes.

12. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Heyn** (U.S. Patent No. **5,201,757**) in view of **Quiachon** (U.S. Pat. No. **5,938,623**).

Claim 52: Heyn discloses the claimed device except for the first conduit comprising a coiled spring.

Quiachon teaches a first conduit **42** comprising a coiled spring **61** (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a coiled spring, as taught by Quiachon, to Heyn since it was known in the art that coiled springs used with conduits, sleeves, sheaths or catheters act as dampeners or absorb vibration along the length of a catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER